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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,917	10/23/2003	Ruchika Singhal	1023-234US01	6514

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SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
01/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairdocketing@ssiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/691,917	SINGHAL ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-19,23-38 and 42-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-19,23-38 and 42-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20081023*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 5-13, 16, 18, 19, 23-30, 32, 35, 36-38, 42-46, and 48-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows et al. (US 6,381,496, hereinafter "Meadows") in view of Sheldon (US 5,593,431, hereinafter "Sheldon"), or in the alternative, over Meadows in view of Sheldon and Daignault, Jr. et al. (US 6,748,276, hereinafter "Daignault").

4. In regards to claims 1, 6, 19, 23, 27, 38, 55, and 56, Meadows discloses monitoring the output of a posture sensor and defining an event based on the monitoring of the sensor output (col. 17, line 66; "e.g. horizontal"); monitoring therapy,

generating therapy information, and associating therapy information with the event (col. 19, lines 1-19; the "OPS" defined by the patient is monitored, saved, and associated with the event); subsequently detecting the defined event and automatically providing therapy to the patient accordingly (col. 18, lines 6-12; the "OPS" defined by the patient and associated with an event is provided); and providing a "prescribed" definition of events (col. 18, line 5). Meadows does not explicitly disclose a calibration step of initially defining an event by storing an indication of the monitored sensor output within a memory. However, Sheldon teaches an implantable medical device comprising an accelerometer and a means for initially defining an event by storing an indication of the monitored sensor output within a memory (e.g., Fig. 13) to provide the predictable results of higher confidence in the accuracy of position determination and offset the misalignment of the IPG axes (col. 15, lines 32-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Meadows' invention by providing a means for initially defining an event by storing an indication of the monitored sensor output within a memory to provide the predictable results of higher confidence in the accuracy of position determination and offset the misalignment of the IPG axes.

5. In regards to the limitations drawn to monitoring and generating therapy "when the event was initially defined," the scope of these limitations are not confined to parallel, simultaneous definition of the event and monitoring therapy/generating therapy information by the processor, consistent with the specification. In other words, "when the event was initially defined," as envisaged by the originally-filed specification means

that these steps occur during the "learning mode," but not necessarily simultaneously and in parallel. As such, "when the event was initially defined" is merely limited to some arbitrary time frame before provision of therapy. Under this reading, Meadows' disclosure of "prescribed" events and OPS (i.e., therapy parameters; col. 18, lines 4-6), the OPS being generated per column 18, line 55 to column 19, line 32, inherently meets the claim limitations because the "events" and "therapy information" are defined/monitored/generated in the arbitrary time frame before the provision of therapy described at column 18, lines 5-10. In other words, the "prescribed OPS" of column 18, line 8 were defined per column 18, line 55 to column 19, line 32 and in the arbitrary time frame before provision of therapy ("when the event was initially defined").

6. In the alternative, Meadows does not explicitly disclose that the "prescribed OPS" are generated by monitoring therapy delivered by the medical device and generating therapy information based on the monitoring of the therapy when the event was initially defined. However, Daignault teaches creating prescribed therapy parameters by monitoring therapy and generating therapy information when events are initially defined (i.e., in the arbitrary time frame before provision of therapy; col. 12, line 44-col. 13, line 30) to provide the predictable result of defining events and therapy that are customized/fitted to a particular patient's body and circumstances. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Meadows' invention by monitoring therapy and generating therapy information when events are initially defined to provide the predictable result of defining events and therapy that are customized to a particular patient's body and circumstances

7. In regards to claims 8, 9, 10, 28, 29, 43, 44, and 45, generating therapy information comprises recording the value/change to a parameter of a therapy parameter, over the time period that the patient is operating the programmer (col. 18, line 55-col. 19, line 19).

8. In regards to claims 11, 30 and 46, the therapy can be delivered based on a combination of events, two of which are an elapsed time and posture change (col. 18, line 5).

9. In regards to claims 12 and 36, the change to the parameter is made with a programming device (Fig. 8).

10. In regards to claims 13 and 35, the parameter is one of amplitude, pulse width, and pulse rate of a neurostimulator (col. 19, line 16).

11. In regards to claims 50, 52, and 54, the device controls pain (col. 1, line 12).

12. In regards to claims 5, 7, 16, 18, 24-26, 32, 37, 42, 48, 49, 51, and 53, Meadows discloses the essential features of the claimed invention including initiating a learning mode in response to a user command (abstract), but does not disclose determining position with a multi-axis accelerometer; defining the event by recording the sensor over a period of time; presenting the defined event to a clinician; or receiving a command from a user to enter a learning mode to define the event. However, Sheldon teaches a IPG device having a means for determining position with a multi-axis accelerometer (abstract) to provide the predictable results determining posture with accepted and usual technology (col. 6, lines 10-15); defining the event by recording the sensor over a period of time (col. 15, line 15) to provide the predictable results of accurately calibrating

the accelerometer to a given implantation configuration; presenting the defined event to a clinician (col. 10, lines 3-24) to provide the predictable results of allowing a physician to monitor the function of the device; and receiving a command from a user to enter a learning mode to define the event (col. 15, lines 38-48) to provide the predictable result of allowing calibration at the user's convenience. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Meadows' invention by providing a means for determining position with a multi-axis accelerometer to provide the predictable results determining posture with accepted and usual technology; defining the event by recording the sensor over a period of time to provide the predictable results of accurately calibrating the accelerometer to a given implantation configuration; presenting the defined event to a clinician to provide the predictable results of allowing a physician to monitor the function of the device; and receiving a command from a user to enter a learning mode to define the event to provide the predictable result of allowing calibration at the user's convenience.

13. Claims 17 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows in view of Sheldon, as applied to claims 16 and 32 above, and further in view of Schallhorn (US 6,120,467, hereinafter "Schallhorn"). Meadows' modified invention discloses the essential features of the claimed invention except for a user interface that presents events as markers within a timing diagram. Schallhorn teaches a device comprising a user interface that presents events as markers within a timing diagram to provide the predictable results of allowing a physician to track patient activity (Fig. 3B). Therefore, it would have been obvious to one having ordinary skill in the art

at the time the invention was made to further modify Meadows' invention by providing a user interface that presents events as markers within a timing diagram to provide the predictable results of allowing a physician to track patient activity.

14. Claims 15 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows in view of Sheldon, as applied to claims 1 and 19 above, and further in view of Stein (US 2002/0038137, hereinafter "Stein"). Meadows' modified invention discloses the essential features of the claimed invention except for suspending delivery of therapy. Stein teaches a device that suspends therapy based on patient activity to provide the predictable results of saving battery life and reducing tolerance to therapy (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Meadows' invention by providing a device that suspends therapy based on patient activity to provide the predictable results of saving battery life and reducing tolerance to therapy.

15. Claims 14, 31, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows in view of Sheldon as applied to claims 8, 27, and 43 above, and further in view of Christopherson et al. (US 5,944,680, hereinafter "Christopherson"). Meadows' modified invention discloses the essential features of the claimed invention except for providing therapy based on a value and time delay received from a user. Christopherson teaches a device comprising providing therapy based on a value and time delay received from a user (col. 26, lines 21-56) to provide the predictable results of conserving energy and reducing artifacts. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was

made to modify Meadows' invention by providing therapy based on a value and time delay received from a user to provide the predictable results of conserving energy and reducing artifacts.

Response to Arguments

16. Applicant's arguments with respect to claims 1, 5-19, 23-38, and 42-56 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762